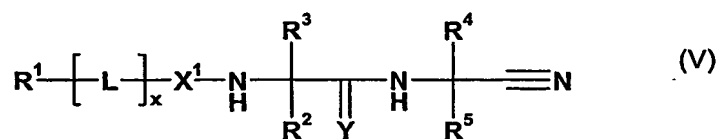


## CLAIMS

1. A method for the treatment of a severe form of bone loss diseases in a patient in need of such treatment which comprises administering an effective amount of a cathepsin K inhibitor to the patient.
2. The use of a cathepsin K inhibitor in the preparation of a medicament for the treatment of a severe form of bone loss diseases.
3. A pharmaceutical composition which incorporates as an active agent a cathepsin K inhibitor for use in the treatment of a severe form of bone loss diseases.
4. A method, use or composition according to any preceding claims, wherein the cathepsin K inhibitors are used to stimulate bone growth in a patient in need of such a treatment.
6. A method, use or composition according to any preceding claims, wherein the diseases are a severe form of osteoporosis, osteoarthritis or bone metastasis.
7. A method, use or composition according to any preceding claims, wherein the disease is severe osteoporosis.
8. A method, use or composition according to any preceding claims, wherein the disease is severe osteoporosis in postmenopausal women.
9. A method, use or composition according to any preceding claims, in which the cathepsin K inhibitor is selected from the following compounds of formula V or a pharmaceutically acceptable salt thereof, or any hydrate thereof



wherein

$R^1$  is optionally substituted (aryl, aryl-lower alkyl, lower alkenyl, lower alkynyl, heterocyclyl or heterocyclyl-lower alkyl);

$R^2$  and  $R^3$  together represent lower alkylene, optionally interrupted by O, S or  $NR^6$ , so as to form a ring with the carbon atom to which they are attached, and  $R^6$  is hydrogen, lower alkyl or aryl-lower alkyl;

$R^4$  and  $R^5$  are independently H, or optionally substituted (lower alkyl or aryl-lower alkyl),  $-C(O)OR^7$ , or  $-C(O)NR^7R^8$ , wherein  $R^7$  is optionally substituted (lower alkyl, aryl, aryl-lower alkyl, cycloalkyl, bicycloalkyl, bicycloalkyl or heterocyclyl), and  $R^8$  is H, or optionally substituted (lower alkyl, aryl, aryl-lower alkyl, cycloalkyl, bicycloalkyl, bicycloalkyl or heterocyclyl); or

$R^4$  and  $R^5$  together represent lower alkylene, optionally interrupted by O, S or  $NR^6$ , so as to form a ring with the carbon atom to which they are attached, and  $R^6$  is hydrogen, lower alkyl or aryl-lower alkyl; or

$R^4$  is H or optionally substituted lower alkyl and  $R^5$  is a substituent of formula  $-X^2-(Y^1)_n-(Ar)_p-Q-Z$  wherein

$Y^1$  is O, S, SO,  $SO_2$ ,  $N(R^6)SO_2$ ,  $N-R^6$ ,  $SO_2NR^6$ ,  $CONR^6$  or  $NR^6CO$ ;

N is zero or one;

P is zero or one;

$X^2$  is lower alkylene; or when n is zero,  $X^2$  is also  $C_2-C_7$ -alkylene interrupted by O, S, SO,  $SO_2$ ,  $NR^6$ ,  $SO_2NR^6$ ,  $CONR^6$  or  $NR^6CO$ , and  $R^6$  is hydrogen, lower alkyl or aryl-lower alkyl;

Ar is arylene;

Z is hydroxyl, acyloxy, carboxyl, esterified carboxyl, amidated carboxyl, aminosulfonyl, (lower alkyl or aryl-lower alkyl)aminosulfonyl, or (lower alkyl or aryl-lower alkyl)sulfonylaminocarbonyl; or Z is tetrazolyl, triazolyl or imidazolyl;

Q is a direct bond, lower alkylene,  $Y^1$ -lower alkylene or  $C_2-C_7$ -alkylene interrupted by  $Y^1$ ;

$X^1$  is  $-C(O)-$ ,  $-C(S)-$ ,  $-S(O)-$ ,  $-S(O)_2-$ , or  $-P(O)(OR^6)-$ , and  $R^6$  is as defined above;

Y is oxygen or sulphur;

L is optionally substituted  $-Het-$ ,  $-Het-CH_2-$  or  $-CH_2-Het-$ , and Het is a hetero atom selected from O, N or S; and

X is zero or one; and

aryl in the above definitions represents carbocyclic or heterocyclic aryl.

10. A method, use or composition according to any preceding claims, in which the cathepsin K inhibitor is N-[1-(cyanomethyl-carbamoyl)-cyclohexyl]-4-(4-propyl-piperazin-1-yl)-benzamide, or a pharmaceutically acceptable salt thereof, e.g. the maleate form, or any hydrate thereof.
11. A pharmaceutical composition comprising less than 50.1 mg N-[1-(cyanomethyl-carbamoyl)-cyclohexyl]-4-(4-propyl-piperazin-1-yl)-benzamide or a pharmaceutically acceptable salt thereof wherein the amount of the base form is less than 50.1 mg.
12. The pharmaceutical composition according to claim 11 comprising less than 64.2 mg N-[1-(cyanomethyl-carbamoyl)-cyclohexyl]-4-(4-propyl-piperazin-1-yl)-benzamide maleate.
13. All novel compounds, processes, pharmaceutical compositions, methods and uses substantially as hereinbefore described with particular reference to the Examples.